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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,574	10/23/2000	Jean-Paul Behr	0652.2090000	9271

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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

26

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/555,574

Applicant(s)

BEHR ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 April 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,2,5-33,37-41,45,46,48 and 49.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The amendment filed August 21, 2003 amends claim 1. This proposed amendment adds the following new limitation to claim 1: "whereby said identical or different organic cationic precursor molecules complex said one or more nucleic acid molecules". This new limitation would require new search and further consideration because the claim as now amended encompasses cationic precursor molecules complexing one or more nucleic acid molecules as opposed to simply binding to nucleic acid molecules. Further, Claim 1 remains rejected for the reasons of record set forth in the previous Office Actions over the breadth of species of functional group of any thiol, acid hydrazide, aldehyde, amine and ethylene as the cationic molecule in the transfection particles. The 35 U.S.C. 112, scope of enablement remains since the transfection particles have specific functional language that must be taken into consideration (ie the requirement that the cationic molecules are made by "condensing said one or more nucleic acid molecules with identical or different organic cationic precursor molecules without crosslinking any of said one or more nucleic acid molecules" and "by linking the precursor molecules to each other with one or more covalent bonds") and thus the claimed molecules as amended must be capable of being made without crosslinking, ie by condensation of the nucleic acid molecules. The previous Office Actions on the merits taught the unpredictability in the art for making such transfection particles.

On page 18 of the response, Applicants argue that the the transfection particles of the instant invention are enabled for one of ordinary skill in the art to use and make. The Examiner agrees that the transfection particles are considered enabled for tranfection of nucleic acids in vitro. However, it is the breath of the claimed transfection particles that is not considered enabled for one of skill in the art to make and use at the time the invention was made for the reasons set forth in the previous Office Actions.

On page 20 of the response, Applicants intend to make the Examiner aware that "crosslinking" and condensation" are not the same. The Examiner is aware that "crosslinking" and condensation" are not the same. The Examiner understands that the nucleic acid molecules condense as a result of the cationic precursor molecule crosslinking with another precursor molecule. The Examiner also understands that the crosslinking occurs between functional groups of the precursor molecules and not the nucleic acids.

On page 21 of the response, Applicants argue that the instant specification provides sufficient guidance to enable the skilled artisan to employ functional groups without undue experimentation. This is not found persuasive because Applicants have not shown which substituted functional groups will exhibit the specific functional language of the claims (ie the requirement that the cationic molecules are made by "condensing said one or more nucleic acid molecules with identical or different organic cationic precursor molecules without crosslinking any of said one or more nucleic acid molecules" and "by linking the precursor molecules to each other with one or more covalent bonds"). Thus, undue experimentation would be required of the skilled artisan to determine which functional groups will meet the functional limitations of the claims.

On page 22 of the response, Applicants argue that the claimed transfection particles are made by DNA condensation and the Examiner's arguments regarding the unpredictability in liposomal formation is not relevant to the predictability of the formation of Applicants' claimed transfection particles. Applicants also argue that the claimed transfection particles are not required to have a liposomal structure. This is not found persuasive because while the claimed transfection particles of the instant invention are not required to have a liposomal structure, the claims are so broad to include those with a liposomal structure. The Examiner relied on the unpredictability of liposomes a they relate to transfection agents for therapeutic use (ie the ability of the transfection agent to pass through the cell membrane of a cell). The function of passing through the cell membrane is what defines those transfection particles with liposomal structures as functional or not. Thus, since the references cited teach the unpredictability of forming such transfection particles having these basic moieties, the same as the instant claimed transfection particles, applicant's arguments are not considered persuasive.


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PRIMARY EXAMINER